# EXHIBIT 17

**IN THE UNITED STATES DISTRICT COURT**
**FOR THE NORTHERN DISTRICT OF FLORIDA**

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| JANE DOE #1, et al.<br><br>Plaintiffs,<br><br>v.<br><br>LLOYD AUSTIN, III, in his official capacity as Secretary of Defense, et al.<br><br>Defendants. | Case No. 1:21-cv-01211-AW-HTC |

**DECLARATION OF PETER MARKS, M.D., Ph.D.**

I, Peter Marks, declare as follows:

1. I am the Director of the Center for Biologics Evaluation and Research ("CBER"), United States Food and Drug Administration ("FDA"), a position I have held since 2016. In this role, I direct the development and implementation of programs and policies for assuring the safety, purity, and potency of biological products, including vaccines, allergenic products, blood and blood products, and cellular, tissue, and gene therapies.

2. I joined FDA in 2012 as the Deputy Director for CBER, after practicing medicine, and working in industry and academia for several years. I received my graduate degree in cell and molecular biology and my medical degree at New York University, am board certified in internal medicine, hematology and medical oncology, and am a Fellow of the American College of Physicians.

3. In my capacity as Director of CBER, I am fully familiar with the instant matter and the facts stated herein. This declaration is based on my personal knowledge, my background, training, and experience and my review and consideration of information available to me in my

official capacity, including information furnished by FDA personnel in the course of their official duties. My conclusions have been reached in accordance therewith.

4. Vaccines are biological products that are regulated under the Public Health Service Act ("PHSA"), 42 U.S.C. § 262(i)(1), as well as "drugs" subject to regulation under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 321(g)(1)(B). Vaccines are approved for marketing through applications known as Biologics License Applications ("BLA"); a vaccine that is the subject of an approved BLA need not also obtain approval of a new drug application ("NDA") under 21 U.S.C. § 355. 42 U.S.C. § 262(a), (j).

5. Under the PHSA, FDA approves a BLA on the basis of a demonstration that: (1) the vaccine is "safe, pure, and potent"[1]; (2) the facility in which the vaccine is produced meets standards designed to assure that the vaccine continues to be safe, pure, and potent; and (3) the applicant consents to inspection of the manufacturing facility. 42 U.S.C. § 262(a)(2)(C). FDA may, but is not required to, consult with its standing advisory committee with scientific expertise in biological products, the Vaccines and Related Biological Products Advisory Committee, as part of the approval process. *See* 21 C.F.R. § 14.171(a). FDA has also issued several guidances and other public documents on biologics and vaccine development. *See generally* Biologics License Applications (BLA) Process, https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/biologics-license-applications-bla-process-cber; Guidance, Compliance & Regulatory Information (Biologics), https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics; Vaccine and Related

[1] The standard for licensure of a biological product as potent under 42 U.S.C. § 262 has long been interpreted by FDA to include effectiveness. *See* 21 C.F.R. § 600.3(s); FDA Guidance, Providing Clinical Evidence of Effectiveness for Human Drug and Biological Products at 4 (May 1998), available at https://www.fda.gov/media/71655/download.

Biological Product Guidances, https://www.fda.gov/vaccines-blood-biologics/biologics-guidances/vaccine-and-related-biological-product-guidances; Vaccine Development 101, https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-development-101.

6. On August 23, 2021, FDA approved a BLA for a COVID-19 vaccine known as Comirnaty, for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older. *See* Comirnaty Approval Letter (August 23, 2021), attached as Exhibit A.

7. Prior to approval, beginning in December 2020, the same formulation of the vaccine, known as Pfizer-BioNTech Covid-19 vaccine, was available under an emergency use authorization ("EUA"). *See* https://www.fda.gov/news-events/press-announcements/fda-takes-key-action-fighting-first-covid-19-issuing-emergency-use-authorization-first-covid-19. FDA has discretion to issue an EUA for an FDA-regulated product if: (1) the Secretary of the Department of Health and Human Services has declared a public health emergency involving a biological or other agent that can cause a serious or life-threatening disease or condition; (2) it is reasonable to believe that the product may be effective in diagnosing, treating, or preventing that disease or condition, and the known and potential benefits of the product outweigh the known and potential risks of the product; and (3 ) there is no "adequate, approved, and available" alternative to the product. 21 U.S.C. § 360bbb-3(c).[2]

[2] Distribution of a product pursuant to an EUA is not a "clinical trial" subject to the requirements for clinical trials conducted under an investigational new drug ("IND") application. 21 U.S.C. §§ 360bbb-3(k); 355(i). Clinical trials must be conducted in accordance with an approved IND and involve only enrolled study participants. Only clinical trial participants enrolled in a clinical study conducted according to an approved IND receive the study drug.

8. Even after FDA approved Comirnaty, FDA authorized continued use of the Pfizer-BioNTech Covid-19 vaccine under an EUA for indications that included the approved use. FDA determined that there is not sufficient approved vaccine available for distribution to the 16 years and older population in its entirety at the time of FDA's reissuance of the EUA. *See* Letter to Pfizer, Inc. reissuing EUA authorization for Covid-19 vaccine, p. 7, n.13 (October 20, 2021), attached as Exhibit B. FDA also determined that there are no products that are approved to prevent COVID-19 in additional populations covered by the EUA, as the vaccine remains available under the EUA for uses that have not been approved, specifically for individuals ages 12 through 15 years old; for a third dose in certain populations; and for a "booster" dose in certain circumstances.

9. Additionally, FDA determined that "[t]he licensed vaccine has the same formulation as the EUA-authorized vaccine and the products can be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns." Letter to Pfizer, Inc. reissuing EUA authorization for Covid-19 vaccine, p. 2, n.8 (August 23, 2021), attached as Exhibit C. FDA provided this information in the Letter of Authorization to make clear that pharmacies and other healthcare practitioners could provide the vaccination series to recipients using Pfizer-BioNTech, Comirnaty, or both (*e.g.*, first dose of Pfizer-BioNTech followed by second dose of Comirnaty, or vice versa), since the products have an identical formulation and are made by the same manufacturer under current good manufacturing practice requirements. FDA included this clarification in the authorization letter to avoid the unnecessary operational complications that may have resulted if pharmacies or other healthcare practitioners had believed that individuals who had received Pfizer-BioNTech for the first dose were not authorized to receive Comirnaty for the second dose, or vice versa.

10. The determination that FDA made for Comirnaty and Pfizer-BioNTech Covid-19 vaccine should not be confused with the statutory interchangeability determination that FDA may make when reviewing a BLA for a biological product manufactured by one company and comparing it with a biological product manufactured by a different company. Under 42 U.S.C. § 262(k)(4), FDA may determine that a biological product is "interchangeable" with a "reference product." "Reference product" is defined at 42 U.S.C. § 262(i)(4) as a "single biological product licensed under [42 U.S.C. § 262(a)] against which a biological product is evaluated in an application submitted under [42 U.S.C. § 262(k)]." The statutory interchangeability determination requires a licensed reference product and a subsequent applicant seeking licensure, which is not present here. The PHSA interchangeability provision also contains obligations related to exclusivity and exchange of patent information for interchangeable products, which would not make sense for two products produced by a single company. *See* 42 U.S.C. § 242(k)(6), (*l*).

11. While FDA determined Comirnaty and Pfizer-BioNTech Covid-19 vaccine are medically interchangeable, there are legal distinctions between BLA-approved and EUA-authorized products. For example, products approved under BLAs are required to have the labeling that was approved as part of the BLA, whereas products authorized under the EUA would have the EUA labeling, and there may also be differences in manufacturing sites for BLA and EUA vaccine. Both the EUA and BLA processes have required the sponsor to identify specific facilities that will manufacture the vaccine. *See* Summary Basis for Regulatory Action – Comirnaty, pp. 12-13 (August 23, 2021), available at https://www.fda.gov/media/151733/download.

12. Vaccine manufactured at sites listed in the BLA also undergoes lot release, which is designed to ensure conformity with standards applicable to the product. 21 C.F.R. § 610.1; *see also* https://www.fda.gov/vaccines-blood-biologics/biologics-post-market-activities/lot-release#lotrelease. Vaccine manufactured at sites that are not listed in the BLA is not subject to the lot release requirement.[3] Both BLA and EUA manufacturing of this vaccine must adhere to FDA's current good manufacturing practice regulations, which are designed to ensure that the products meet specified standards of purity and potency. *See* 21 C.F.R. Part 211 (CGMP regulations for drugs), § 211.1(b) (applicability of CGMP regulations to drugs that are also biological products); EUA Reauthorization at 11 (Sept. 22, 2021), available at https://www.fda.gov/media/150386/download.

13. In conjunction with the approval of Comirnaty, FDA asked the applicant to identify available lots of vaccine that were manufactured at facilities listed in the BLA that had undergone lot release. For these lots and other lots produced at facilities listed in the BLA, at this time, FDA is exercising its enforcement discretion with respect to certain labeling requirements, in that FDA is not taking enforcement with respect to vials that bear the EUA label.[4] FDA considers these lots to be manufactured in compliance with the BLA and they are not subject to the EUA requirements when used for the approved indication. Thus, the conditions in the Letter

[3] Although not subject to lot release, as a condition of the EUA, Pfizer submits to the EUA file Certificates of Analysis for each drug product lot at least 48 hours prior to vaccine distribution; these Certificates include the established specifications and specific results for each quality control test performed on the final drug product lot. Additionally, also as a condition of the EUA, Pfizer submits quarterly manufacturing reports to the EUA file that include specified information about each lot of vaccine manufactured. *See* Exhibit B at 11-12.

[4] Each vial contains six doses of vaccine and a dose is withdrawn from the vial immediately before injection into a recipient, who would not ordinarily be handling the vial or viewing its label. Fact Sheet for Healthcare Providers Administering Vaccine, pp. 6-8 (Sept. 22, 2021), available at https://www.fda.gov/media/144413/download.

of Authorization for the EUA—including the condition requiring vaccination providers to provide recipients with the Fact Sheet for Recipients, which advises recipients that "under the EUA, it is your choice to receive or not receive the vaccine"—do not apply when these lots or other BLA-compliant lots are used for the approved indication. FDA worked with the Applicant to develop a Dear Healthcare Provider letter and website to identify those lots. Summary Basis for Regulatory Action – Comirnaty ("SBRA"), p. 27 (Aug. 23, 2021), attached as Exhibit D. Also, for operational efficiency, to account for the fact that recipients may receive either the BLA or EUA vaccine, after licensure of Comirnaty, vaccine has been distributed with unified Fact Sheets, one for providers and one for recipients, that provide information regarding the EUA product, as well as information about the licensed product. *See* Fact Sheet for Recipients (Sept. 22, 2021), available at https://www.fda.gov/media/144414/download.

14. FDA has programs to expedite the development of drugs that are being studied to treat life-threatening or severely debilitating diseases. 21 U.S.C. § 356. These programs, one of which is "Fast Track" designation, are designed to help ensure that therapies for serious conditions are approved and available for patients as soon as it can be concluded that the therapies' benefits outweigh their risks. *See* Guidance for Industry, Expedited Programs for Serious Conditions – Drugs and Biologics (May 2014), available at https://www.fda.gov/media/86377/download. Fast Track designation was granted for Comirnaty on July 7, 2020. *See* Exhibit D, SBRA at 5. As explained on FDA's website, "Once a drug receives *Fast Track* designation, early and frequent communication between the FDA and a drug company is encouraged throughout the entire drug development and review process. The frequency of communication assures that questions and issues are resolved quickly, often leading

to earlier drug approval and access by patients." https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track.

15. In addition to granting Comirnaty "Fast Track" designation, FDA took other steps to speed development and review of COVID-19 vaccines in response to the urgent public health threat posed by SARS-CoV-2, without sacrificing the stringent statutory requirements for approval. Vaccines typically undergo three phases of clinical trial. *See* https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/vaccine-development-101. Phase 1 generally involves 20 to 100 healthy volunteers and focuses on safety. *Id.* Phases 2 and 3 studies typically enroll more subjects and are designed to gather more safety information on common short-term side effects and risks, examine the relationship between the dose administered and the immune response, and generate critical efficacy data. *Id.* In the case of the COVID-19 vaccines, those phases overlapped to speed the development process; no phases were skipped. *See* 21 C.F.R. § 312.21 ("Although in general the phases are conducted sequentially, they may overlap."). Also, because COVID-19 continues to be widespread, the vaccine clinical trials have been conducted more quickly than if the disease were less common.

16. The Comirnaty BLA was approved based on six months of safety and efficacy data from two ongoing clinical trials, C4591001 and BNT162-01, as well as safety information from the millions of vaccine doses administered under the EUA. C4591001 is a randomized, placebo-controlled, combined Phase 1, 2, and 3 study that has enrolled more than 43,000 participants. *See* Exhibit D, SBRA at 15. Initially, during Phases 2 and 3, study participants, as well as study investigators/personnel collecting and evaluating safety and efficacy information were blinded to

the participants' treatment assignment (observer-blinded).[5] The study population for Phase 2/3 includes participants at higher risk for acquiring COVID-19 and at higher risk of severe COVID-19, such as participants working in the healthcare field, participants with autoimmune disease, and participants with chronic but stable medical conditions such as hypertension, asthma, diabetes, and infection with HIV, hepatitis B or hepatitis C. *Id.* at 16.

17. In accordance with C4591001's study protocol (the plan that describes the objectives, design, methodology, statistical considerations, and organization of a clinical trial, *see* Glossary of Clinical Trial Terms, *available at* https://www.fda.gov/media/108378/download#:~:text=A%20document%20that%20describes%20the,in%20other%20protocol%20referenced%20documents), participants ages 16 and older in C4591001 have been progressively "unblinded" since the December 2020 issuance of the EUA for the Pfizer-BioNTech Covid-19 vaccine and offered the vaccine if they were randomized to the placebo group. Exhibit D, SBRA at 17. The study was unblinded in stages, either when participants were eligible according to local recommendations for vaccination or after conclusion of their six-month post–Dose 2 study visit (whichever was earlier). *Id.* Despite the unblinding, the data collected during the clinical trial still allowed FDA to evaluate the safety and

[5] "Blind" means that one or more parties of the clinical trial are kept unaware of the treatment assignment. Study participants, investigators, and health care providers may all be blinded to the treatment a participant is receiving, for example, whether a study participant is receiving the study drug or a placebo. Glossary of Clinical Trial Terms, *available at* https://www.fda.gov/media/108378/download#:~:text=A%20document%20that%20describes%20the,in%20other%20protocol%20referenced%20documents). Blinding may be done to prevent skewing of the data by the placebo effect, by risk-seeking behavior, by unconscious bias or by other factors. Blinding may impose a significant burden on the volunteer trial participants, and medical ethicists generally agree that researchers are sometimes ethically bound to unblind a study and permit placebo recipients to receive an effective treatment at some point. The availability of effective treatment also encourages participation in clinical trials. Overall, the decision regarding when to "unblind" a clinical trial involves a delicate balance of competing priorities.

effectiveness of the vaccine, considering the data collected during the blinded stage and the other information submitted supporting safety and effectiveness. Although C4591001 is ongoing and safety will be evaluated for the duration of the study for blinded and unblinded participants, because most adverse events linked to vaccination occur within two months of vaccination (*see* Table VI. National Vaccine Injury Compensation Program. Rockville, MD: Health Resources and Services Administration, 2017 (https://www.hrsa.gov/sites/default/files/hrsa/vaccine-compensation/vaccine-injury-table.pdf.), FDA determined that a BLA for a COVID-19 vaccine could be supported by six months of safety data.[6] *See* FDA Guidance, Development and Licensure of Vaccines to Prevent COVID-19, at 15 (June 2020), attached as Exhibit E. Because the applicant submitted sufficient safety and efficacy data, the ongoing nature of the phase 3 clinical trial was not a basis for declining to license Comirnaty. The estimated completion date for C4591001 is May 2023, *see* https://www.clinicaltrials.gov/ct2/show/NCT04368728?term=C4591001&draw=2&rank=4).

18. BNT162-01 an ongoing Phase 1/2, open-label, dose-finding study with 24 participants, designed to evaluate the safety and immunogenicity of several candidate vaccines, including the dose that was approved by FDA on August 23, 2021. *See* Exhibit D, SBRA at 15. Safety data from the study was included in the BLA for Comirnaty and supported selection of the

[6] Indeed, requesting six-months of follow-up safety data is not unique to Covid-19 vaccines. *See* Guidance for Industry Clinical Data Needed to Support the Licensure of Pandemic Influenza Vaccines, at 5,7, 10 (May 2007), available at Guidance for Industry: Clinical Data Needed to Support the Licensure of Pandemic Influenza Vaccines (fda.gov) (generally recommending six-months of safety data to support influenza vaccines). FDA explained the rationale for requesting at least six-months of safety data to support licensure of Comirnaty in its response to a Citizen Petition submitted by the Informed Consent Action Network ("ICAN"), raising concerns similar to those raised by Plaintiffs. *See* Response to ICAN Citizen Petition, Docket FDA-2021-P-0529, at 9-10 (August 23, 2021), available at https://www.regulations.gov/document/FDA-2021-P-0529-1077.

final vaccine candidate and dose level. *Id*. at 21. Although FDA did not refer the BLA to its advisory committee, the agency considered the committee's feedback from prior meetings considering the EUA for the Pfizer-BioNTech Covid-19 vaccine. *Id.* at 26-27.

19. In addition to reviewing clinical data, before approving the Comirnaty BLA, FDA assessed, among other things, its chemistry, manufacturing, and controls ("CMC"); nonclinical and clinical pharmacology and nonclinical toxicology data; safety and pharmacovigilance data; labeling; and manufacturing facilities. *See* 21 C.F.R. § 601.2 (requirements for contents of BLA application). Along with the Summary Basis for Regulatory Action for Comirnaty, also available on FDA's website for the Comirnaty BLA review are three Statistical Reviews; an assessment of Real World Evidence; two Pharmacovigilance Plan Reviews; two CMC Reviews, Clinical Review; CBER Sentinel Program Sufficiency Review; Bioresearch Monitoring Review; Benefit-Risk Assessment Review; Analytical Method Review; and Toxicology Review. *See* https://www.fda.gov/vaccines-blood-biologics/comirnaty (click on Approval History, Letters, Reviews, and Related Document – COMIRNATY).

20. Based on the data from the two clinical studies, FDA determined that the overall efficacy rate in the 16 and older subject population was 91.1% for the prevention of COVID-19 infection and between 95% and 100% for the avoidance of severe infection. Exhibit D, SBRA at 19-20. FDA also considered the safety data from the two clinical studies, in addition to safety information from EUA use. *Id.* at 22-25. In sum, based on its review of the clinical, pre-clinical, and product-related data submitted in the Comirnaty BLA, FDA determined that the product had a favorable benefit/risk balance, and was safe, pure, and potent. The agency approved the license for Comirnaty on August 23, 2021. *Id.* at 27-28; Exhibit A, FDA Approval Letter (Aug. 23, 2021).

21. Comirnaty is subject to specified post market requirements and commitments. *See* 21 U.S.C. §§ 355(o)(2)(B)(ii) and 356b. Those requirements and commitments are: (1) Study C4591009, entitled "A Non-Interventional Post-Approval Safety Study of the Pfizer-BioNTech COVID-19 mRNA Vaccine in the United States," to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY; (2) Study C4591021, entitled "Post Conditional Approval Active Surveillance Study Among Individuals in Europe Receiving the Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine," to evaluate the occurrence of myocarditis and pericarditis following administration of COMIRNATY; (3) Study C4591021 sub-study to describe the natural history of myocarditis and pericarditis following administration of COMIRNATY; (4) Study C4591036, a prospective cohort study with at least 5 years of follow-up for potential long-term sequelae of myocarditis after vaccination; (5) Study C4591007 sub-study to prospectively assess the incidence of subclinical myocarditis following administration of the second dose of COMIRNATY in a subset of participants 5 through 15 years of age; (6) Study C4591031 sub-study to prospectively assess the incidence of subclinical myocarditis following administration of a third dose of COMIRNATY in a subset of participants 16 to 30 years of age; (7) Study C4591022, entitled "Pfizer-BioNTech COVID-19 Vaccine Exposure during Pregnancy: A Non-Interventional Post-Approval Safety Study of Pregnancy and Infant Outcomes in the Organization of Teratology Information Specialists (OTIS)/MotherToBaby Pregnancy Registry"; (8) Study C4591007 sub-study to evaluate the immunogenicity and safety of lower dose levels of COMIRNATY in individuals 12 through < 30 years of age; (9) Study C4591012, entitled "Post-emergency Use Authorization Active Safety Surveillance Study Among Individuals in the Veteran's Affairs Health System Receiving Pfizer-BioNTech Coronavirus Disease 2019 (COVID-19) Vaccine"; (10) Study C4591014, entitled

"Pfizer-BioNTech COVID-19 BNT162b2 Vaccine Effectiveness Study - Kaiser Permanente Southern California"; (11) Deferred pediatric study C4591001 to evaluate the safety and effectiveness of COMIRNATY in children 12 years through 15 years of age; (12) Deferred pediatric study C4591007 to evaluate the safety and effectiveness of COMIRNATY in children 6 months to < 12 years of age; and (13) Deferred pediatric study C4591023 to evaluate the safety and effectiveness of COMIRNATY in infants < 6 months of age. Exhibit D, SBRA at 29-30.

22. On the same day that FDA approved the license for Comirnaty, the agency responded to a Citizen Petition submitted by the Coalition Advocating for Adequately Licensed Medicines (CAALM) on July 23, 2021. CAALM Petition, Docket FDA-2021-P-0786, attached as Exhibit F. Among other things, the petition requested that FDA require "substantial evidence of clinical effectiveness that outweighs harms in special populations such as: infants, children, and adolescents; those with past SARSCoV-2 infection; immunocompromised; pregnant women; nursing women; frail older adults; and individuals with cancer, autoimmune disorders, and hematological conditions" before licensing a Covid-19 vaccine, and that there should be information about "what kind of efficacy" exists for these populations, referring to "reduction in risk of symptomatic COVID-19 vs. reduction in risk of hospitalization or death." *Id.* at 2. Some of the populations identified by petitioners participated in the clinical trials and additional information will be obtained from post-marketing studies. For example, approximately 3% of the clinical trial participants had evidence of prior Covid-19 infection (*see* Clinical Review Memo at 35, referenced in paragraph 19, above). Additionally, although pregnant individuals were excluded from participation in the trial and the applicant has committed to study the vaccine in this population segment as described in paragraph 21 above, participants in both the treatment and placebo arms of the trial became pregnant during the trial, and pregnancy

outcomes of spontaneous abortion, miscarriages and elective abortions was similar between the vaccine and the placebo group. *Id.* at 84. In response to CAALM's Citizen Petition, FDA concluded that petitioners had not provided sufficient scientific justification for requiring effectiveness data from clinical trials specific to each population group and specifically designed to evaluate disease endpoints of varying severity, and petitioner's argument was not consistent with "scientifically valid methods of assessing safety and effectiveness," such as immunobridging or extrapolation across population groups. CAALM Petition Response at 7-8 (August 23, 2021), attached as Exhibit G.

23. FDA also considered and responded to petitioner's claims that people previously affected with COVID-19 "are likely to have immunity to subsequent infections for as long or longer than immunity conferred by vaccine" and "may also be at heightened risk for adverse effects" from the vaccine, finding there was scientific uncertainty about the duration of immunity from natural infection and that petitioners had not provided sufficient scientific support for the latter claim. CAALM Petition Response at 8-9, n.31. In reaching that conclusion, FDA evaluated each study put forward by petitioners and carefully explained why the studies did not support petitioner's arguments. *Id.; see also* Response to ICAN Citizen Petition at 13-15.

24. In approving the BLA for Comirnaty, FDA applied its scientific expertise to evaluate the data contained in the application and determined that Comirnaty's benefits outweigh its risks and that it is safe, pure, potent, and effective for its proposed use. In response to the urgent public health emergency presented by COVID-19, FDA worked expeditiously to provide guidance to entities seeking to develop vaccines for this disease, and to review the BLA for Comirnaty once it was submitted to the agency to ensure it fully met the statutory standards for approval, to further the objective of protecting the public health.

25. I have reviewed the Declaration of Jane Ruby submitted in this matter. ECF No. 1-18. Although I have not attempted to exhaustively analyze her conclusions, the declaration is rife with error and appears to reflect a lack of basic knowledge of the field. For example, I disagree with Ms. Ruby's assertion that the phased unblinding of participants in C4591001 renders the data from the trial "completely compromised." *See id.* at ¶12. As explained above in paragraph 17 and in FDA's Clinical Review at 26, referenced in Paragraph 19 above, that participants initially assigned to the placebo arm of the study were unblinded in phases in accordance with the protocol does not invalidate the data generated in the trial. Ms. Ruby's declaration also erroneously references C4591001's original exclusion criteria, *id.* at ¶15, without regard to subsequent protocol amendments to add study populations, interventions, and analyses not included in the original design, one of which permitted enrollment of HIV-infected trial participants. *See* FDA's Clinical Review at 23, referenced in Paragraph 19 above. Ms. Ruby is also incorrect in stating that FDA did not consider the pharmacokinetics of the vaccine (Ruby Decl. at ¶16). *See* FDA's CMC Review at 115, also referenced in Paragraph 19 above. In Paragraph 24 of her declaration, Ms. Ruby evidences a fundamental misunderstanding of the clinical trial process when she impliedly criticizes the protocol for C4591001 for permitting doses of the vaccine greater than 3 times the dose that was approved. In fact, one of the purposes of clinical trials to establish the appropriate dose of a medication and the very protocol cited by Ms. Ruby explains precisely how clinical data led to the dose that was ultimately approved. *See* Ruby Decl. Exhibit E at 40 (ECF No. 1-18 at 83). These examples are just illustrative of the many errors in Ms. Ruby's declaration.

26. An injunction against the licensure of Comirnaty would cause irreparable harm. Safe and effective vaccines are currently the most powerful tool we have against the pandemic and

have been estimated to have already saved hundreds of thousands of lives. An injunction here would call into question the data supporting FDA's determination that Comirnaty is safe and effective. The consequence could be to undermine the vaccine development process, if vaccine developers see that courts are willing to disregard FDA's rigorous review process and remove products from the market on the basis of mere allegations. In addition, another consequence could be to seriously undermine the government's efforts to encourage vaccination in all eligible populations by exacerbating vaccine hesitancy. One of the most significant barriers to widespread vaccination is vaccine hesitancy and vaccine misinformation. It would also create considerable public and administrative confusion as to the effect of the injunction because the identical formulation has been authorized pursuant to an EUA. Even a more limited injunction, somehow limited to these plaintiffs, would generate extraordinary doubt and confusion.

I declare under penalty of perjury that the foregoing is true and correct to the best of my information, knowledge, and belief.

Dated: October 21, 2021

Peter Marks

Peter Marks, M.D., Ph.D.
Director, Center for Biologics Evaluation
and Research
United States Food and Drug Administration